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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,508	01/26/2004	Mark W. Kroll	A04P1007	2562

36802 7590 12/05/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,508

Applicant(s)

KROLL, MARK W.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 17 and 18 is/are rejected.
- 7) ☒ Claim(s) 8-16 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: "the time duration of the selected feature" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 5-7 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girouard et al. (2004/0093034) in view of Olson et al. (5,779,645).

Regarding claims 1, 17 and 18, Girouard shows an apparatus and corresponding method that includes sensing means (20, 21, 30, 31, 40, 41) for sensing cardiac activity to provide an electrogram of the sensed cardiac activity; integrating means (10) for integrating a selected feature of the electrogram to provide an integral (area under the curve) (paras. [0005], [0021]-[0022]); and detecting means for detecting ischemia when the electrogram feature score satisfies a given criteria (paras. [0005],[0021]-[0022]); claims 6 and 16). Although Girouard fails to show normalizing means, attention is directed to Olson who shows normalizing means for normalizing an integral (area under the curve) by a normalizing factor to provide an electrogram feature score (Col. 5, lines 46-65; Col. 7, lines 58-64; Col. 8, line 56-Col. 9, line 43). Olson teaches that normalizing the integral (area under the curve) significantly reduces computational complexity, reduces the complexity of waveform morphology diagnosis, conserves power and

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extends battery life (Col. 3, lines 36-39; Col. 38-41). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the apparatus and corresponding method of Girouard to include a normalizing means for normalizing an integral (area under the curve) by a normalizing factor to provide an electrogram feature score as taught by Olson in order to significantly reduce computational complexity, reduce complexity of waveform morphology diagnosis, conserve power and extend battery life.

With respect to claim 2, Girouard shows the selected electrogram feature is an ST segment (paras. [0021]-[0022]).

Regarding claim 5, Girouard shows the sensing circuit (20, 21 30, 31, 40, 41) and processor (10) are enclosed within a conductive case and wherein the at least two electrodes include the case (60) (Fig. 1A).

With respect to claim 6-7, Girouard shows the at least two electrodes further include one of a ring electrode (33a, 43a) and a tip electrode (23, 33b, 43b) (Fig. 1A) and the at least two electrodes are a ring electrode and a tip electrode (Fig. 1A).

4. Claim 3 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Girouard et al. (2004/0093034) in view of Olson et al. (5,779,645) as applied to claim 1 above and further in view of Nearing et al. (2005/0010122). Girouard and Olson are as explained before. However, Girouard and Olson fail to teach the normalizing factor is an R-wave amplitude. Attention is directed to Nearing who teaches normalizing (scaling) ECG signals associated with T-waves and ST segments utilizing an R-wave amplitude normalizing factor. Nearing teaches that normalizing the ECG signal with the R-wave amplitude permits comparison of ECG signals of different individuals to one another and will compensate for low amplitude signals due to disease

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or poor electrode signals [paras. [0060], [0098]]. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the apparatus of Girouard and Olson to include an R-wave amplitude normalizing factor as taught by Nearing in order to permit comparison of ECG signals of different individuals to one another and compensate for low amplitude signals due to disease or poor electrode signals.

5. Claim 4 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Girouard et al. (2004/0093034) in view of Olson et al. (5,779,645) as applied to claim 1 above and further in view of MacAdam et al. (2002/0091330). Girouard and Olson are as explained before. However, Girouard and Olson fail to teach the normalizer is a divider and the divider divides the integral by the time duration of the selected feature. However, attention is directed to MacAdam who teaches normalizing ECG segments utilizing a divider as a normalizer that divides the integral by the time duration of the selected feature [para. 0068]. MacAdam teaches that utilizing a time duration of the selected feature for normalization provides a way for comparing two separately obtained ECG segment integrals. It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the apparatus of Girouard and Olson to include a divider as a normalizer that divides the integral by the time duration of the selected feature as taught by MacAdam in order to provides a way for comparing two separately obtained ECG segment integrals

Allowable Subject Matter

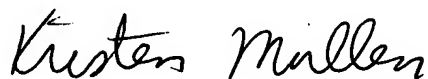
6. Claims 8-16 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen D. Mullen
Patent Examiner-Temp. Full Signatory
Authority
Art Unit 3766

kdm